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OFFICE OF
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MEMORANDUM

SUBJECT: Distribution of the "Radiation Risk Assessment At CERCLA Sites: Q&A"

FROM: for Robin H. Richardson, Acting Director
Office of Superfund Remediation and Technology Innovation

TO: Superfund National Policy Managers, Regions 1–10

Purpose

The purpose of this memorandum is to transmit the final guidance "Radiation Risk Assessment At CERCLA Sites: Q&A." This new final guidance will replace a previous version of the "Radiation Risk Assessment At CERCLA Sites: Q&A" issued in 1999.

Role of the Guidance

The Office of Superfund Remediation Technology Innovation (OSRTI) developed this document to present an overview of current EPA guidance for risk assessment and related topics for radioactively contaminated Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) remedial sites. It provides answers to several commonly asked questions regarding risk assessments at radioactively contaminated CERCLA remedial sites.[1] The purpose of this document is to provide answers to commonly asked questions regarding risk assessment for radioactive contamination, describe how to analyze levels of radioactive contamination and explain how to assess the risks from radioactive

[1] The document transmitted by this memorandum provides guidance on risk assessment under CERCLA and is consistent with the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). It does not alter the NCP's general expectations for remedial actions, such as those regarding treatment of principal threat waste and the use of containment and institutional controls for low-level threat waste. Consistent with CERCLA and the NCP, remedial actions need to attain or waive Applicable or Relevant and Appropriate Requirements (ARARs); potential ARARs for contaminated ground water at radiation sites typically include Maximum Contaminant Levels (MCLs) or non-zero Maximum Contaminant Level Goals (MCLGs) established under the Safe Drinking Water Act.

This document provides guidance to U.S. Environmental Protection Agency (EPA) staff on how to conduct risk assessments for radioactively contaminated CERCLA sites. The guidance is designed to be consistent with EPA's national guidance on these issues. This guidance does not, however, substitute for EPA's statutes or regulations, nor is it a regulation itself. Thus, it cannot impose legally binding requirements on EPA, states, or the regulated community, and may not apply to a particular situation based upon the circumstances. EPA may change this guidance in the future, as appropriate.

contamination as part of a remedy for a radioactively contaminated CERCLA remedial site. This guidance is intended to help health physicists, risk assessors, remedial project managers, and others involved with risk assessment and decision making at CERCLA remedial sites with radioactive contamination.

Background

The EPA issued guidance entitled "Establishment of Cleanup Levels for CERCLA Sites with Radioactive Contamination" (OSWER No. 9200.4-18, August 22, 1997). This 1997 guidance provided clarification on establishing protective cleanup levels for radioactive contamination at CERCLA sites. The guidance reiterated that cleanups of radionuclides are governed by the risk range for all carcinogens established in the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) when Applicable or Relevant and Appropriate Requirements (ARARs) are not available or are not sufficiently protective. Cleanups generally should achieve a level of risk within the 10^{-4} to 10^{-6} carcinogenic risk range based on the reasonable maximum exposure for an individual. In calculating cleanup levels, one should include exposures from all potential pathways, and through all media (e.g., soil, ground water, surface water, sediment, air, structures, etc.) The guidance also provides a listing of radiation standards that are likely to be used as ARARs to establish cleanup levels or to conduct remedial actions.

The EPA previously issued "Radiation Risk Assessment At CERCLA Sites: Q&A" (OSWER No. 9200.4-31P, December 1999). The 1999 Risk Q&A provided an overview of the then current EPA guidance for risk assessment and related topics for radioactively contaminated CERCLA sites. This guidance provided answers to several commonly asked questions regarding risk assessments at radioactively contaminated CERCLA sites. In addition, it recommended that dose assessments only be conducted under CERCLA where necessary to demonstrate compliance with ARARs. Today's Risk Q&A guidance updates the 1999 version of the Risk Q&A by summarizing and citing guidance that was developed after the 1999 version. This new guidance explains how to convert radon measurements to demonstrate compliance with indoor radon standards that are potential ARARs using a methodology based on international guidance, and it changes the Superfund recommendation on what is considered a protective dose-based ARAR from 15 to 12 millirem per year (mrem/yr). The new recommendation of 12 mrem/yr regarding what dose-based ARARs are protective is based on using an updated risk assessment to achieve the same 3 x 10^{-4} cancer risk as the previous recommendation using 15 mrem/yr.

The Radiation Risk Q&A guidance is part of a continuing effort by OSRTI to provide updated guidance for addressing radioactively contaminated remedial Superfund sites consistent with our guidance for addressing chemically contaminated sites (while accounting for the technical differences between radionuclides and chemicals). OSRTI intends for this effort to facilitate remedial cleanups that are consistent with the NCP at radioactively contaminated sites and to incorporate new information based on improvements to the Superfund program.

Implementation

For questions regarding radiation site policy and guidance for CERCLA cleanup actions, readers are referred to the Superfund Radiation Webpage at http://www.epa.gov/superfund/health/contaminants/radiation/index.htm. The subject matter specialist for this guidance is Stuart Walker of OSRTI. He can be reached by e-mail at walker.stuart@epa.gov or by telephone at (703) 603-8748.

Q3. What criteria should be used to determine areas of radioactive contamination or radioactivity releases?

During the site assessment phase, Section 7 of EPA's revised Hazard Ranking System (HRS) (see Appendix A to 40 Code of Federal Regulations [CFR] Part 300) outlines the methodology for evaluating radioactive releases and determining whether a radioactive release is a high priority for the CERCLA remedial program.

During risk assessments, guidance for the measurement and evaluation of radiological contaminants is provided in the *Soil Screening Guidance for Radionuclides* (Rad SSG) documents (U.S. EPA 2000a, 2000b). The Rad SSG also provides guidance on the determination of site-specific background levels for comparison to site measurements. The Soil Screening Levels (SSLs) are not cleanup standards, but may be used to inform further investigation at sites. The SSL risk assessment equations have been superseded by those in the PRGs calculator where applicable or relevant and appropriate requirements (ARARs) are not available or sufficiently protective; therefore, the PRG calculator should be used for determining SSL risk based concentrations rather than the Rad SSG documents.

General guidance to inform the evaluation of radiological contamination is provided in the following Agency documents:

- *Methods for Evaluating the Attainment of Cleanup Standards—Volume 1: Soil and Soil Media* (U.S. EPA 1989b)
- *Statistical Methods for Evaluating the Attainment of Cleanup Standards—Volume 2: Ground Water* (U.S. EPA 1992a)
- *Statistical Methods for Evaluating the Attainment of Cleanup Standards—Volume 3: Reference-Based Standards for Soils and Solid Media* (U.S. EPA 1992b)

Although these documents do not specifically address radionuclides, most of the evaluation methods and tests provided in these documents should be applicable to both radioactive and nonradioactive contaminants.

There are two general sampling approaches for determining what is contaminated for site characterization or demonstrating compliance with cleanup levels; a not-to-exceed (NTE) or area averaging (AA) approach. In general, the same sampling approach should be used for both radionuclide and chemical contaminants in the same medium at the same site (e.g., soil, groundwater, surface water, air, or buildings) to facilitate a consistent approach for addressing radionuclides and chemicals; generally, samples for both should be collocated in the media of interest. For groundwater contamination, EPA's Superfund remedial program generally recommends an NTE approach. EPA's Superfund remedial program general practice has been to use the NTE approach for soil where residential land use is assumed. If using the AA approach, users should ensure that exposure of receptors across the exposure unit is random. However, exposure is not expected to be random under residential land use because residents often engage in activities (such as gardening or child's play) in specific portions of a yard. Under most residential situations and other non-

excess cancer risks are additive for evaluating the total incremental cancer risk associated with a contaminated site.

Q30. How should risk characterization results for radionuclides be presented?

A. Results should be presented according to the standardized reporting format presented in *RAGS* Part D (U.S. EPA 1998a). EPA guidance for risk characterization (U.S. EPA 1995a, 1995b) indicates that four descriptors of risk are generally needed for a full characterization of risk: (1) central tendency (such as median, mean) estimate of individual risk; (2) high-end estimate (for example, the 95th percentile) of individual risk; (3) risk to important subgroups of the population, such as highly exposed or highly susceptible groups (such as children) or individuals, if known; and (4) population risk. The reasonable maximum exposure (RME) estimate of individual risk typically presented in Superfund risk assessments represents a measure of the high-end individual exposure and risk. While the RME estimate remains the primary scenario for Superfund risk management decisions, additional risk descriptors may be included to describe site risks more thoroughly (e.g., central tendency, sensitive subpopulations). Population risk is generally not used as part of Superfund risk assessments.

Q31. Is it necessary to present the collective risk to populations estimated along with that to individual receptors?

A. Generally, no. Risk to potential RME individual receptors generally is the primary measure of protectiveness under the CERCLA remedial process (the target range of 10^{-6} to 10^{-4} lifetime excess cancer risk to the RME receptor). As noted in Q30, however, Agency guidance (U.S. EPA 1995a, 1995b) also indicates that the central tendency risk to the potentially exposed population may be evaluated where possible. Consideration of central tendency risk may provide additional input to risk management decisions; such considerations may be either qualitative or quantitative, depending on the availability of data.

Q32. How should uncertainty in estimates of radiation risk be addressed in the risk characterization report?

A. Consideration of uncertainty in estimates of risks from potential exposure to radioactive materials at CERCLA sites typically is an essential element of informed risk management decisions. *RAGS* and subsequent guidance (U.S. EPA 1995a, 1995b) stress the importance of a thorough presentation of the uncertainties, limitations, and assumptions that underlie estimates of risk. Either qualitative or quantitative evaluation may be appropriate, depending on the availability of data and the magnitude of predicted risk. In either case, the evaluation should address both uncertainty ("the lack of knowledge about specific factors, parameters, or models") and variability ("observed differences attributable to true heterogeneity or diversity in a population or exposure parameter"). Estimates of potential risk should include both central tendency estimates (median, mean) and high-end estimates (such as RME or 95th percentile).

Extrapolation from high dose and dose rate exposure is generally done to estimate risks of low-level exposures for both chemical carcinogens and radionuclides. This extrapolation typically constitutes the greatest source of uncertainty. Additional uncertainty may be introduced due to extrapolation of animal data to humans for chemical carcinogens. Slope factors for both radionuclides and chemicals are used to estimate incremental cancer risk, which typically represents a small increment over a relatively high baseline incidence. It should be noted that there is less uncertainty associated with the slope factors for radionuclides than any, or almost any, chemical slope factors since the radionuclide slope factors are based primarily on human rather than animal data. Other sources of uncertainty may be associated with instrumentation and measurements used to characterize the nature and extent of radionuclides of concern, and the parameters used to characterize potential exposures of current and future receptors (such as intake rates and frequency of exposure).

Probabilistic Risk Assessment (PRA) may be used to provide quantitative estimates of the uncertainties in the risk assessment. However, probabilistic estimates of risk should be presented as a supplement to, not instead of, the deterministic (point estimate) methods outlined in *RAGS* Part A. A tiered approach is often useful, with the rigor of the analysis depending on the magnitude of predicted risk. Factors to be considered in conducting a probabilistic analysis typically should include the sensitivity of parameters, the correlation or dependencies between parameters, and the distributions of parameter values and model estimates. Detailed guidance on this topic is provided in *Use of Probabilistic Techniques (Including Monte Carlo Analysis) in Risk Assessment* (U.S. EPA 1997c) and *Guiding Principles for Monte Carlo Analysis* (U.S. EPA 1997d).

Q33. When should a dose assessment be performed?

A. Dose assessments should be conducted during CERCLA remedial responses only when considering compliance of clean up plans with dose-based ARARs. As discussed in OSWER Directive 9200.4-18 (U.S. EPA 1997a), cleanup levels for radioactive contamination at remedial sites should be established as they would for any chemical that poses an unacceptable risk and the risks should be characterized in standard Agency risk language consistent with CERCLA guidance for remedial sites. Thus, **cleanup levels not based on an ARAR should be based on the carcinogenic risk range (generally 10^{-4} to 10^{-6}, with 10^{-6} as the point of departure and 1 x 10^{-6} used for PRGs) and expressed in terms of risk (# x $10^{-\#}$).**

Q34. What is the upper end of the risk range with respect to radionuclides?

A. Consistent with existing Agency guidance for the CERCLA remedial program, while the upper end of the risk range is not a discrete line at 1 x 10^{-4}, EPA generally uses 1 x 10^{-4} in making risk management decisions. A specific risk estimate around 10^{-4} may be considered acceptable based on site-specific circumstances. For further discussion of these points and how EPA uses the risk range, see OSWER Directive 9355.0-30, *Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions* (U.S. EPA 1991d). In general, dose assessment used as a method to assess risk is not recommended as a way of ensuring protectiveness of human health at CERCLA remedial sites.

Q35. Should the ARAR protectiveness criteria evaluation recommendation be changed from 15 mrem/yr to reflect the updates to radiation risk estimates contained in Federal Guidance Report 13?

A. **Yes, ARAR protectiveness criteria evaluation recommendation of 15 mrem/yr should be changed to 12 mrem/yr to reflect the current federal government position on the risks posed by radiation, which is contained in EPA's Federal Guidance Report 13 (U.S. EPA 1999c)**. More recent scientific information reflected in EPA's Federal Guidance Report 13 risk estimates show that 12 mrem/yr is now considered to correspond approximately to 3 x 10^{-4} excess lifetime cancer risk. This *updated approach is based on FGR 13's assumption of a risk of cancer incidence* of 8.46 x 10^{-4} per rem of exposure (while still using the EPA CERCLA standard period of exposure of 30 years for residential land use, which also was the basis of the 15 mrem/yr determination in OSWER Directive 9200.4-18). Therefore, the ARAR evaluation guidance first discussed in OSWER Directive 9200.4-18 is being updated to 12 mrem/yr so that ARARs that are greater than 12 mrem/yr effective dose equivalent (EDE) are generally not considered sufficiently protective for developing cleanup levels under CERCLA at remedial sites. As before, this ARAR evaluation tool should not be used as a to be considered (TBC) as a basis for establishing 12 mrem/yr cleanup levels at CERCLA remedial sites.

Please note that the prior references to 15 mrem/yr in OSWER Directive 9200.4-18 were intended as guidance for the evaluation of potential ARARs and TBCs factors and **should not be used as a TBC for establishing 15 mrem/yr cleanup levels at CERCLA sites**. Consistent with that guidance, using 15 mrem/yr as an ARAR evaluation tool originally was based on three factors:

1. The CERCLA risk range for remedial sites. In 1997, 15 mrem/yr was estimated to correspond to approximately 3 x 10^{-4} under the then EPA practice of using the dose to risk estimate conversions assumption of a risk of cancer incidence of 7.6 x 10^{-4} per rem of exposure, found in ICRP 1991 and NAS 1990. This dose to risk estimate has been superseded by the assumption of a risk of cancer incidence of 8.46 x 10^{-4} per rem of exposure in FGR 13 (U.S. EPA 1999c).
2. Prior EPA radiation rulemakings, and
3. Prior EPA CERCLA site-specific decisions.

Q36. Should dose recommendations from other federal agencies be used to assess risk or establish cleanup levels?

A. Generally, no. **Dose assessments generally should only be performed to assess risks or to establish cleanup levels at CERCLA remedial sites** to show compliance with an ARAR that requires a dose assessment (for example 40 CFR 61 Subparts H and I, and 10 CFR 61.41). Dose level recommendations from international and other non-EPA organizations are not enforceable and therefore cannot be ARARs. The selection of cleanup levels for carcinogens for CERCLA remedy selection purposes should be consistent with the NCP and CERCLA guidance – i.e., based on the risk range when

ARARs are not available or are not sufficiently protective. EPA has made the policy decision to use the NCP's risk range in developing cleanup levels for radionuclides at CERCLA remedial sites rather than using dose-based guidance since the use of dose-based guidance. See Q10 for more information on this determination.

EPA recommends using the DCC, BDCC, and SDCC calculators (U.S. EPA 2004a, 2010a, and 2010b) to develop dose assessments for ARAR compliance purposes at Superfund remedial sites. As indicated on page 2 of the memorandum transmitting the DCC calculator (U.S. EPA 2004c), that guidance superseded the dose assessment equations in Chapter 10 of *RAGs* Part A (U.S. EPA 1989a).

Q37. How and when should exposure rate be used to estimate radionuclide risks?

A. **As discussed previously (see Q25 and Q28), EPA recommends that estimates of radiation risk should be derived using slope factors, in a manner analogous to that used for chemical contaminants.** However, to ensure protectiveness of human health consistent with CERCLA and the NCP requirements for the remedial program, there may be circumstances where it is desirable at CERCLA remedial sites to also consider estimates of risk based on direct exposure rate measurements of penetrating radiation in addition to risk estimates based on slope factors. Examples of such circumstances where it may be appropriate to also use direct measurements for assessing risk from external exposure to penetrating radiation include:

- During early site assessment efforts when the site manager is attempting to communicate the relative risk posed by areas containing elevated levels of radiation,

- As a real-time method for indicating that remedial objectives are being met during the conduct of the response action. The use of exposure rate measurements during the conduct of the response actions should not decrease the need for a final status survey.

To facilitate developing risk estimates under any of these situations, EPA is developing a Counts Per Minute (CPM) calculator (U.S. EPA 2014a) to model correlations in exposure rate measurements back to modeled estimates of cancer risk. Direct radiation exposure rate measurements may provide important indications of radiation risks at a site, particularly during early investigations, when these may be the first data available. However, these data may reflect only a subset of the radionuclides and exposure pathways of potential concern (for example, only external exposure from gamma-emitting radionuclides in near-surface soil), and may present an incomplete picture of site risks (such as risk from internal exposures, or potential increased future risks from radionuclides in subsurface soils). In most cases, more accurate estimation of radiation risks will require additional site characterization data, including concentrations of all radionuclides of concern in all pertinent environmental media. The principal benefit of using direct exposure rate measurements is the speed and convenience of analysis, and reducing the potential for missing areas of contamination. **However, exposure rate data generally should be used in conjunction with characterization data of radionuclides concentrations**